§ 173.115 Alpha-acetolactate decarboxylase (α-ALDC) enzyme preparation derived from a recombinant Bacillus subtilis.

The food additive alpha-acetolactate decarboxylase (α -ALDC) enzyme preparation, may be safely used in accordance with the following conditions:

- (a) The food additive is the enzyme preparation derived from a modified $Bacillus\ subtilis\ strain\ that\ contains\ the$ gene coding for $\alpha\text{-ALDC}$ from $Bacillus\ brevis$.
- (b)(1) The manufacturer produces the additive from a pure culture fermentation of a strain of *Bacillus subtilis* that is nonpathogenic and nontoxigenic in man or other animals.
- (2) The manufacturer may stabilize the enzyme preparation with glutaraldehyde or with other suitable approved food additives or generally recognized as safe substances.
- (3) The enzyme preparation must meet the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 4th ed., 1996, pp. 133-134, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal_register/
 code of federal regulations/

code_of_federal_regulations/ibr_locations.html.

(c) The additive is used in an amount not in excess of the minimum required to produce its intended effect as a processing aid in the production of alcoholic malt beverages and distilled liquors.

[66 FR 27022, May 16, 2001]

§ 173.120 Carbohydrase and cellulase derived from Aspergillus niger.

Carbohydrase and cellulase enzyme preparation derived from *Aspergillus niger* may be safely used in food in ac-

cordance with the following prescribed conditions:

- (a) Aspergillus niger is classified as follows: Class, Deuteromycetes; order, Moniliales; family, Moniliaceae; genus, Aspergillus; species, niger.
- (b) The strain of *Aspergillus niger* is nonpathogenic and nontoxic in man or other animals.
- (c) The additive is produced by a process that completely removes the organism *Aspergillus niger* from the carbohydrase and cellulase enzyme product.
- (d) The additive is used or intended for use as follows:
- (1) For removal of visceral mass (bellies) in clam processing.
- (2) As an aid in the removal of the shell from the edible tissue in shrimp processing.
- (e) The additive is used in an amount not in excess of the minimum required to produce its intended effect.

§ 173.130 Carbohydrase derived from *Rhizopus oryzae*.

Carbohydrase from *Rhizopus oryzae* may be safely used in the production of dextrose from starch in accordance with the following prescribed conditions:

- (a) Rhizopus oryzae is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, Rhizopus; species, Rhizopus oryzae.
- (b) The strain of *Rhizopus oryzae* is nonpathogenic and nontoxic.
- (c) The carbohydrase is produced under controlled conditions to maintain nonpathogenicity and nontoxicity, including the absence of aflatoxin.
- (d) The carbohydrase is produced by a process which completely removes the organism *Rhizopus oryzae* from the carbohydrase product.
- (e) The carbohydrase is maintained under refrigeration from production to use and is labeled to include the necessity of refrigerated storage.